Information Exchange Workgroup
Subgroup 1
Draft Transcript
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Presentation

Operator

Ms. MacKenzie, all lines are bridged.

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good afternoon everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Policy Committee's Information Exchange Workgroup, Subgroup #1. This is a public call, and there will be time for public comment at the end. The call is also being transcribed, so please be sure to identify yourself before speaking. I will now take roll. Micky Tripathi?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Micky. Amy Zimmerman? Peter DeVault?

Peter DeVault – EPIC Systems Corporation

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Peter. Dave Goetz?

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Dave. Hunt Blair? And are there any Workgroup members on the line? Are there any staff members?

Claudia Williams – Office of the National Coordinator

Claudia Williams.

MacKenzie Robertson – Office of the National Coordinator

Hi, Claudia. Okay, I'll turn the call over to you, Micky.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay, great. Thank you, and thanks everyone for joining today. We are Subgroup #1, which means that we're going to be looking at the governance RFI comments of a few of the high-level governance RFI comments from the early parts of the RFI. And in particular, I think there are three questions that are priority questions for this subgroup. I think it's probably deceptive that there are only three, because I think there may be a bunch of issues related to these, but let's see how far we get. It strikes me in just looking at these—and Dave and Peter, I don't know if you had a chance to take a quick look at what questions we're going to be looking at in this—

Amy Zimmerman – Rhode Island Department of Health & Human Services

Micky? By the way, this is Amy, and I just joined.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Oh, great. Thanks, Amy. We've got question five, which is about establishing a national validation process, whether it would relieve the burden on states to regulate local and regional health information exchange markets, and then question six about how do we ensure alignment between the governance mechanism and existing state governance approaches. So those two are somewhat related. But then there's this question 56, which is sort of a broad, sweeping, overall one, which I don't know if there's context for this, but it—this says: Which CTEs would you revise or delete, and why, which I think applies to all of the CTEs. Is that correct? Claudia or Tari, do you know?

Claudia Williams – Office of the National Coordinator

That is correct.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay. So that one, unless any of us has ideas on the full scope and the full universe of the CTEs and have thoughts on any, I almost wonder whether that should be one that we come back to, as a workgroup perhaps, on Tuesday after we've been able to take stock of where all the subgroups are and what that would all suggest for deletion of any of the CTEs or revision?

Amy Zimmerman – Rhode Island Department of Health & Human Services

Just because I'm so acutely aware of the one hour we have … group in submitting our comments, one option would be to put out a call to the whole workgroup and say, "If you have suggestions for ones to delete or add, please send them to Micky by Monday." We need to reach resolution within an hour of that meeting, which might make it tricky to wait until then. But I think we could put a call out to everyone and say this is one that requires broad input.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay. Tari's been following these closely, and I've been participating on as many of the subgroup calls as I can. I mean, it seems like some of the conclusions imply deletion of a CTE, for example. We haven't stated it, but it may be that some of that just sort of comes out from a reading of the comments.

Claudia Williams – Office of the National Coordinator

Sure.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay, so why don't we focus then on question five and question six, and then we can dive into the secondary questions and get as far as we do, but we certainly want to attack the priority ones. So on the first one: Would establishing a national validation process as described above effectively relieve any burden on the states to regulate local and regional health information exchange markets? I've been on two calls today that actually saw this 180-degree different. One, I think, was the information exchange workgroup call where there seemed to be a sense—and we weren't addressing this question, but it was in looking at the workgroup #3 recommendations. There seemed to be a sense that having some type of national process does relieve some type of burden on states or on any organizations who are looking at this.

Then I was on another call for another organization that is preparing comments, and there was someone there from a very large, multi-state provider organization whose view on this was that his reading of the RFI was that it didn't alleviate any burden on the states, and indeed, that they as a provider organization operating in multiple states saw this national process as being just another layer and burdensome in that way, that they were already going to have to live with the state layers and that this was going to be yet another layer for them to have to deal with. I was surprised to see those two.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah. Well, it depends on the actions of the states, I guess. This is Dave Goetz; I'm sorry. I mean, if they, in fact, treat this as it's treated in other areas where they would deem these to be sufficient—deem compliance to be sufficient—then you relieve the burden on the state, and you relieve the burden—I mean, you see this in other kind of accreditation bodies, for NCQA for example, deem compliance with accreditation for NCQA as sufficient to meet what are often more general state statutory requirements.

But to the extent that in these cases state laws—we all know of a couple of states at least that go well beyond what other states would consider a minimum. Maybe the better model is HIPAA and where states have gone beyond on HIPAA, and to think about it that way and whether that has, in fact—how burdensome that has been on multi-state organizations.

Amy Zimmerman – Rhode Island Department of Health & Human Services

This is Amy, Micky. And as you were saying that, I was thinking—I think it is actually potentially a little bit of both. So I think, to some extent, depending on the type of provider organization that's doing the exchange and depending on the state laws and how—whether they regulate exchange per se or not—and depending on the state laws, I think it could—eventually over time, could regulations in state law reference this validation or accreditation process as sufficient? My answer would be possibly and potentially, depending on how their own state laws align or don't align with some of the CTEs.

And there's so much variability around some, depending on sort of where the state laws—I was trying to think, and I don't know JACO really well, but I was trying to think hospitals—there's still states who have a lot of regulations for hospitals. How much JCI accreditation can count towards that or doesn't count towards that? I mean, I don't know if that's the model to sort of think about and look about because I don't know enough about the hospital regs and JCI accreditation. I was just trying to think about other examples where there might be a parallel to whether—I think over time, it might be able to, but I think it's very circumstantial, which is why I think you're getting differing opinions.

Claudia Williams – Office of the National Coordinator

This is Claudia. Just for some background that kind of, I think, informs some of the question. As far as we know, there's only one state that regulates, that actually has laws on the books regulating—not from a privacy standpoint, but from a standpoint of looking at the range of issues that we might look at here, and that's Minnesota. And there are a few others that have accreditation processes, or, like, the Rhode Island Trust Community and things like that.

So I think at least the intent of what we were looking at was not necessarily the complete range of areas where states regulate around what can be shared and privacy and your health information and all of that, but a little more strictly looking at the sets of things around interoperability, security, things like that. And there were a few states stepping up, and some wondering if they should. We saw a relatively small number that were but had gotten some feedback that they were like, "We're only doing this because there's not something else to rely on." So that's just some framing, not that it—just to help understand the questions that we were asking.

Amy Zimmerman – Rhode Island Department of Health & Human Services

But, Claudia, so with that comment, where do you see the privacy and security component to the CTEs and whether it alleviates or doesn't alleviate state regulatory responsibility?

Claudia Williams – Office of the National Coordinator

Well, I guess just that the governance rule isn't trying to set a comprehensive privacy framework. It's addressing a relatively … set of issues around interoperability, security, authentication. It's not saying this is the kind of information you can share.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Right. So my point is that the state regulations are still going to—that potentially state law or state regulations could go beyond what is here. Does it put an extra burden on? No, because those providers have to end up complying with state—those exchanges or entities or organizations that are doing health information exchange in that state still have to abide by whatever state law or regulation.

Peter DeVault – EPIC Systems Corporation

This is Peter DeVault. It seems like there are two areas that we might be talking about, one of which just could help alleviate the states' burden. To the degree that this is offering a national accreditation approach, it might relieve the burden on the states, but the states are still going to have to have the burden of actually coming up with the laws that describe the CTEs or other certification requirements for their states. It doesn't relieve the burden of actually coming up with which CTEs are important and which …

Amy Zimmerman – Rhode Island Department of Health & Human Services

Right, which is, if I'm understanding you correctly, why I think wholesale saying that the entire certification or validation or accreditation process may not fully alleviate the state need to regulate.

Peter DeVault – EPIC Systems Corporation

That's right. They'll have to regulate, but they might not have the burden of actually doing the accreditation. That can be delegated.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Right.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

And they just deem it again like … in other areas. I mean, it would be the simplest way to—the minimalist way for a state to do it, right?

Peter DeVault – EPIC Systems Corporation

Yes.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

So in a way, it sounds like part of the—there's a two-part answer here or something. One might be just would establishing a national validation process effectively relieve any burden. It depends a little bit on whether we're setting that bar high or low, right?

Peter DeVault – EPIC Systems Corporation

Maybe I'm misunderstanding, but I thought at the national level this is all voluntary, so it's not even setting a floor. So even the reference to HIPAA is not a great metaphor for this because there actually is no national floor above which they can go, right? It's a menu of options that they might choose to incorporate in their own legislation.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, I guess what I was getting at is that if there is a national validation process, and it's going to have—this is just saying a validation process, and that validation process is going to be—the content of that validation process is going to be determined by all or the other CTEs that are under discussion in various other places or various other subgroups.

But I guess what I was getting at is if you set that bar really low, meaning that it is very easy to get accredited, that that may not relive any burden on the states, or states that feel inclined to regulate, that's because they may feel that it doesn't really resolve whatever issues they feel need to be resolved by accreditation. Minnesota and Rhode Island may still go ahead with whatever they're going to do, or New York, because the bar is so low.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

So what would be the gap between what Minnesota currently requires and the CTEs that we are looking at? I'm on page 56, 57, since that's kind of a convenient summary of all of them, because a number of these impress—if it's functionality, in other words, encryption for the information, that doesn't rise to, it seems to me, a level of something that is—a state is not going to say don't encrypt, right? And I wouldn't think they would say encrypt to this standard, that they would let that be determined by the market and what's deemed to be functional. I don't know; I'm trying to distinguish what a state would consider its purview and what's in the CTEs.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Well for example—I mean, this isn't the case in Rhode Island—but the CTEs, it talks about—I think in the privacy and security area you find most of them—so for states that maybe opt-out currently now or are doing things—and now this is talking about meaningful choice, so here the bar, the CTE, might be higher. I mean, one would say opt-out is still choice, but how they go about offering and implementing that according to a state law may vary. I'm trying to just skim through and see if there are any that apply that I can think of what the case in Rhode Island.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Right. I think—

Amy Zimmerman – Rhode Island Department of Health & Human Services

Or even if …operated services with high availability and targeted—no, I don't know if there would be state law on that, but—I'm probably not thinking of an example right now, but I could probably if I—

Dave Goetz – OptumInsight – Vice President for State Government Solutions

The only one that has given me any pause as a—well, not the only one—but the one that's given me any pause as I've tried to think about it is S-10. I'm unclear as to how that is accomplished. And the implication of that is that there is—it seems to me that there is an opt-in requirement. So does that interfere with a state that wants to remain in opt-out, or does it mandate an opt-in requirement and in essence, when you combine that with the idea of direction, at the direction of the patient's direction in the next one, the interoperability one? Are there things like that that combine to then limit or direct state policymaking?

The other things about, again, encryption, stuff like that, I'm not sure that does.

Claudia Williams – Office of the National Coordinator

I'm just taking a quick look at S-10. This is Claudia. S-10 wasn't referring to a consent. It was referring to whether a provider was accessing information for a current patient, if that makes sense.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

No, I get that, Claudia, but I'm just wondering how you'd actually, in a practical sense, effectively do that without having—

Claudia Williams – Office of the National Coordinator

Yeah, so a lot of HIEs, like in Delaware, do things like: "Have you ordered a lab for this patient? Do I see a connection between the patient and provider? Is it a referral? I mean, there are a lot of algorithmic ways to do that—or just attesting that you are in a relationship. So there are—

Dave Goetz – OptumInsight – Vice President for State Government Solutions

You mean like creating a document repository, in essence?

Claudia Williams – Office of the National Coordinator

… lot of ways it's been done, some of which relied just on I attested I'll only access information for patients.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, I was going to say I think … one is a self-attestation when you go to get the information on a queried response, you're saying, "Yes, I have a treating relationship with the patient."

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah but assuming—again, maybe this is a wrong assumption—but assuming that there is some auditing requirement that comes in behind that … on NVEs and sub-NVEs, if you will, as to compliance, I guess you could deem attestation is compliance, but that may or may not be meaningful.

Claudia Williams – Office of the National Coordinator

So I'm hearing two—at least two things. One is that since it's a much broader range of issues, let's say, around sensitive data or around whatever that states are regulating today, obviously this would not relieve those burdens. To the extent that they are anticipating or currently regulating in this area, their ability to rely on it will depend on how rigorous it is. And they could either do that by just saying, "We no longer have to regulate," or they could do that by regulating but by deeming this accreditation as meeting their regulations.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

I think that's broadly true, and I don't think that—again, I don't think a lot of these things would be implicated by how their policies towards sensitive information and opt-in, opt-out, you know, those things. I think that's—

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. So it sounds like we're saying at the margins maybe it could slightly relieve burden, but it's not—in general it doesn't sound like it. The things that they care about are going to be related to privacy and security—or privacy—and they're probably going to continue to do that.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

And appropriately so.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. Yep.

Claudia Williams – Office of the National Coordinator

But then the domains in which this is covering, perhaps it could, right?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay, does that—

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, I think that captures it. I mean, I think basically what we're saying is there's a little bit of a mix here.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Right.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Tari, you feel like you've got enough to develop a coherent comment on that?

Tari Owi – Office of the National Coordinator

I believe so.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Make us sound coherent anyway.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah. No, she's quite good at taking muck and turning it into something clear, so that's good. Okay, and so how about the second then? How can we ensure alignment between the governance mechanism and existing state governance approaches? So this is to the extent that there are formalized state governance approaches, right? I mean, most states it sounds like don't have really a formalized governance approach.

Peter DeVault – EPIC Systems Corporation

Correct.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

The simplest way would be to ask them to do an analysis of the differences—again like I was talking about with Minnesota, right? I mean, what is the gap? Do you see any gaps, and what are they? And have that come back to the governing body for just definitions so that somebody else could look at it who is interested in coming into a particular state and say, "Okay, well this is what the state believes is the differences between the national guidelines and standards and what they do in their own state. That make sense?

Peter DeVault – EPIC Systems Corporation

It does. On the other hand, it's kind of a difficult question to answer given that there may, in fact, someday be different state governance approaches. I mean, I hope not, but it's almost that we'd rather have the states align with what we're coming up with.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah, I understand that. I'm trying to get to the idea though that this is kind of, again, voluntary, and if the state is going to be enforcing what it sees is the differences because it believes it has authority and responsibility to do that, it would be good to at least have documented somewhere what they think that is so you'd know what to expect as an NVE.

Amy Zimmerman – Rhode Island Department of Health & Human Services

You mean on a state-by-state basis?

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah. I mean, if they would do a gap analysis on all this between what they believe their authority is and what the standards or guidelines say.

Amy Zimmerman – Rhode Island Department of Health & Human Services

And when you say "they," you mean the state?

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah, because, again, they're the ones who are going to come to you as an NVE operating in a state and say, "You do this, but you have to do this in addition," or, "This is how we've interpreted these particularly CTEs.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Well, not the state as—this is Micky—

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah, you may be right.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, because the state has the regulatory authority over this. There's no authority that HITECH has over them on this.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yep.

Amy Zimmerman – Rhode Island Department of Health & Human Services

I really tried to think about this, and this was sort of tough. I think the issue is to the extent that states feel that they can use this and incorporate it because there is some alignment into whatever laws or regulations they're putting in place. So to some extent it sounds kind of silly, but to the extent that individuals working at this at the state level are aware—and policymakers—and see whether it can work to their advantage, there can be alignment.

Like I said before, I think that there are going to be instances and cases where either these CTEs don't go far enough, or the state has a variation in its approach where there isn't alignment. And especially on a voluntary program, I don't know that—certainly states are sensitive to what are the national standards and where is the federal government going, and to the extent that funding requests or other things get tied to this, then that does become a driver.

But states and legislatures, like in general assemblies, they like to kind of have a mind of their own, and they really don't always really—I mean, the state official policymakers, like in state agencies, tend to be very sensitive to that. And I'm not saying general assembly and legislators don't, but if there is a reason or a need locally, they're going to sort of go with whatever local politics drive them. I mean, at least that's my sense.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. Yeah, in a way I was just thinking about that. I was going on the same lines, Amy, which is just that the question isn't necessarily framed in the way that is most relevant, I think, for the way the dynamics of this really play out, which is to say that it's not necessarily a burden on the states because, at least in my experience, there are many states who have an unquenchable desire to regulate.

So where this will be helpful is actually to those of us in the private sector who are trying to convince a state not to do something. At least that's where I find myself often in the states where I'm working is to try to be able to have arguments like for EHR certification for example. That's a great example. And multiple states have been dealing with state legislatures who want to create state-level standards for EHRs, and I think we've been able to successfully argue that there are federal standards for this, and point to those, and that seems to sort of tame that desire.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

HIPAA also is instructive there because there are states that went beyond HIPAA minimums, but they were—generally there was a strong effort across the country to say, "Look, HIPAA set the minimum. Just do that so that we can operate in a multi-state environment."

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, well coming from a state that went beyond HIPAA specially for the purposes of health information exchange but from a statewide HIT perspective, that didn't hold because the view was completely different, that we're talking a whole different game here now. We're talking a lot of my information all potentially available through one approach, and all bets are off; rules are different now.

The other part to this is that, again, when I go back and think about, "So why in Rhode Island did we put a law in place?" Now, the law in Rhode Island is mostly privacy and security, but it gives the Department of Health the responsibility to regulate our state-designated entity/RIO, and we only had one official one in the state that's covered under that. Are there private HIEs? Yes. Are they bound by the law? No, which is kind of interesting in and of itself. But the reason we went there is because the general public, the stakeholders, had concerns about privacy and security, and wanted to codify things to make them feel better in law.

If you look at it, Micky, from your perspective, for private sector it may be helpful to the extent that the public understands that there is some national standard and believes that it is protecting them. There may be less of a push from the stakeholder community, or from the general consumer public patient community, to want to then have something regulated in this regard. I don't know.

But that's a little different than alignment. To the extent that there are a lot of states that aren't really doing any regulation in this area, then if this comes in and doing a lot of education and figuring out how to make this—since it is voluntary—really get the uptake going and make it so that it's not overly burdensome, then that may alleviate the need for states that haven't gone there to go there.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Amy Zimmerman – Rhode Island Department of Health & Human Services

And how it aligns with where our state law is a whole other question, and what it would change or not change, I don't know.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

As we were just describing, there's no—we're just looking at question six again—but there's no formal authority that HITECH has over states' regulatory abilities of information exchange. I mean, it seems like the question goes back to—well, the kind of alignment that is desired between a federal governance kind of approach and states' rights around certain things that there's no formal authority over is the regular orchestration of policy levers where you get them to do things through other means, right? You tie Medicaid HIE funding to agreement with the CTEs, for example, and a whole bunch of other policy levers that could be pulled. It's usually about tying funding to those kinds of things.

Claudia Williams – Office of the National Coordinator

One of the framing pieces in the whole RFI is that we at the federal level decided not to both describe an accreditation process and describe how we as federal people would use it within our other policies. But just as you've described, the RFI said—for instance, Medicare could say it's only going to use an accredited agency for sharing information for claims attachments, as an example. So I think you're pointing out an important point that similarly states could call on this in various things. But I think you made the point, Amy, that that only works if a lot of people are participating. But that's also forced participation.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Well, state employee health plans are a good vehicle for that stuff.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

So it sounds like where we are on this is that there is no formal way to do that. But as we were just describing—and, I think, Claudia, thanks for reminding me, there is a section in the preamble that actually talks about this—that there are various levers that the federal government could pull to get alignment for this even though they don't have direct authority over the states' ability to regulate in this area.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yes, you can get alignment and say you need this. Again, then in states where there may be regulations that differ, then somehow the driver is to either have the state have to change its law or be out of compliance … law or regulations or be out of compliance or somehow force that—see how to make those come together.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right, and it may be that you fall back to, like we are in public health and meaningful use, that it becomes then an unless-prohibited-by-law kind of condition.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Right.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

So does that generally capture where we are in this? Yeah? Tari, you got that?

Tari Owi – Office of the National Coordinator

I do.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay. Alright, so 56 we're not going to address right now, correct?

Amy Zimmerman – Rhode Island Department of Health & Human Services

If we have time, I think it's a good idea to get as much done as we can unless you have other general comments.

Claudia Williams – Office of the National Coordinator

You just wanted to go on to the secondary?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, I'm saying to go on to the secondary. I mean, I'd love to just say, "Okay, we're done; it's Friday afternoon." But yeah, I was suggesting that we go on the secondary just because I think 56 is just too broad to really address in a systematic way unless any—and I certainly don't want to cut off anyone who feels that they have a view on any CTEs that ought to be revised or deleted right now.

Claudia Williams – Office of the National Coordinator

Hey, Micky, I'm just wondering do you guys find this whole discussion is really an answer to five, and we didn't—we kind of said, well, six is sort of not really that relevant? Or did you guys feel like we were parsing a separate response for both?

Dave Goetz – OptumInsight – Vice President for State Government Solutions

I felt like we were doing a separate response for both. Maybe I missed it.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, I think I did too.

Peter DeVault – EPIC Systems Corporation

Yeah.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, I agree.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Maybe in the writing it'll seem like they come together.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Maybe we weren't clear on how we'd addressed alignment. Maybe that's the issue.

Claudia Williams – Office of the National Coordinator

That's what I was just saying. I think what we were saying is alignment didn't really feel like the right question.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Claudia Williams – Office of the National Coordinator

Tari, as she writes, will make a recommendation.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. Yeah.

Amy Zimmerman – Rhode Island Department of Health & Human Services

In my mind, one of the things we said around alignment is in order to align, you have to understand the differences and you have to also educate. and then you can sort of drive alignment. You can drive it by attaching the validation or accreditation process to funding, which then sort of forces state government, if they want to get that funds, to have to figure out how to accept or modify. Or you put in caveat as accepted by law, and then you're not really aligning—but over time maybe you could.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Amy Zimmerman – Rhode Island Department of Health & Human Services

I mean, those were sort of the points that came out in terms of the conversation in terms of actual strategies. but I think we did then all say, "Yeah, but this question is kind of a weird question." Not weird, but just maybe not the right question.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yep.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Does that help, Claudia?

Claudia Williams – Office of the National Coordinator

Yeah, …

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Massachusetts, I think, was the last state in the Union to accept right on red. And they resisted all the way to the end until the federal government said, "You won't get a dollar in federal highway funds until you do this."

Claudia Williams – Office of the National Coordinator

I know because I was a teenager when they did it.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Then I think the next year the state went through and put up "No Right on Red" signs for three-quarters of the intersections. The state preempts them. Okay, so should we dive into the secondary questions then, unless anyone feels strongly about a particular CTE that you want to talk about revising or deleting? But it feels like that might be a better offline exercise.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, I think so.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay, the first question here is about—let me just see how many questions we have. Okay, so it looks like five. Here's seven. So the first question here is about the categories themselves and do they comprehensively capture what we would think of as governance over the nationwide health information network. And those categories are: business practices, interoperability, and safeguards. Certainly, at least from my perspective, and I can start—I mean, as I was thinking about that and moving from the high level to the actual CTEs, I couldn't think of a particular category or anything that wasn't captured somewhere—whether I would use the same names or not is a separate question.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

The only one that's ever given me any trouble is interoperability, just whether that's …

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay. Right. So this is getting to the question of are they needed to be governed as opposed to—

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Well, maybe I have a different definition in my head of what interoperability is. That may be the problem.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. So maybe there's two parts to this. I was just thinking about those categories cover everything that one would think of as governance, but there's a second question of is it appropriate to have federal imposition in each of those categories, which was sort of the second and seemingly fair question, that maybe that you think that there is governance needed for the NwHIN, but not necessarily in every category.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Well, I struggled a little bit about this is governance for the When, but does an NVE need its own governance in some way? I mean, there are various kinds of NVEs, and how does that relate? And does business practices, does it—and maybe it's the term—does that sufficiently cover operations and administration? I mean, it probably does.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Well there's only—yeah, so I'm just looking at the slide here—there are three in Steve's—under business practices.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Where are you going for the secondary questions, Micky? I'm sorry. Maybe I missed that. Is it in an e-mail?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, sorry. It's in the document that was sent around a few days ago.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Okay.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

There was a—oh, wait a minute. You know what? I may be looking at the wrong one. Yeah, I'm sorry. I was looking at—hold on. Yeah, I have the subgroup—sorry, I have the—oh, no, this is the right one.

Claudia Williams – Office of the National Coordinator

The attachment we had originally sent, I think, said subgroup #2, but it was really subgroup #1. It should have questions five and six at the top and questions one, two, three, at the—

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah.

Claudia Williams – Office of the National Coordinator

But we can—do you need that, Dave?

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah, if you could pump it to me real quickly. I thought I had it, but I'm struggling to dig through the mountain of e-mail.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

One question is do we—is there a general category of these CTEs, whether it's specific CTEs or a category of CTEs, that we think should not be governed from the federal level?

Amy Zimmerman – Rhode Island Department of Health & Human Services

Can someone just explain to me business practice two, what is trying to be said there that an NVE must provide open access to the directory services it provides to enable planned electronic exchange? What do we mean by open access to directory services?

Claudia Williams – Office of the National Coordinator

The idea here is that each NVE might be maintaining its own directory services for its own client, but those need to be query-able so that somebody could route information from another NVE to somebody in that NVE.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, and I'll just add that this was—

Claudia Williams – Office of the National Coordinator

We also could choose to look at that one question, but that would be—the categories here are the sort of more business practices … fair—creating a level playing field, assuring that the business is reliable, that they're accepted kind of organization, and …

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, so for that specific one, for example, with subgroup #2—yes, it was subgroup #2—I think they're going to be—we'll be discussing this on Monday, their recommendations. One set of them is going to be about what are essentially net neutrality principles. So there would be this idea that from NVE to NVE, there ought to be basically free, basic dial-tone services available across NVEs, and then you would define what are those dial-tone services, and I think one of them would be open access to directories across—so one NVE couldn't charge another NVE, for example, to give access to its directory service. It might be able to charge them for a whole bunch of other things, you know, value-added things. But that would be one of the things that you would say for net neutrality principles we ought to call that dial tone.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah, I mean, you can't hide a group of them or whatever.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. So it seems to me if we just sort of walk through this and—I mean, I may be looking at this wrong, but just to give everyone something to react to. So on the business practices, just thinking about that, it seems certainly appropriate for some level of some federal floor being laid here in the business practice area related to, as I said, just basic net neutrality principles, for example.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Net neutrality really creeps me out. I heard that on the call a little bit earlier just because of the whole table thing, right? But I get what they're saying on that, but I'm trying to think of maybe there's a better term.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

It creeps you out? Did it creep you out when you worked for the state government, or is it just …

Dave Goetz – OptumInsight – Vice President for State Government Solutions

It's just the idea. It's just that I think of Comcast, and maybe that's what my problem … with it. But what you're wanting is open access, right? I mean, you're wanting—

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Maybe that's the way to think about it. Okay, so the principle of business practices is to not allow anyone to restrict the ability of one provider to communicate with another provider, right?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. But not being so stringent that you don't allow people to legitimately charge for value-added types of services that ought to be a part of things that they can develop commercially.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Right.

Claudia Williams – Office of the National Coordinator

… I'm wondering if—it feels like the conversation is going into specifics. I wonder if that means that folks don't have complaints? They don't have either ones they want to add or ones they want to take away as far as categories? And then we could move on to the next one.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Yeah, not today.

Claudia Williams – Office of the National Coordinator

Okay.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay, so if we go to number two then: What kind of governance approach would best produce a trusted, secured interoperability and interoperable electronic exchange nationwide? That's a nice, tight, narrow question. Joking.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Benign dictatorship—oh.

Amy Zimmerman – Rhode Island Department of Health & Human Services

I have a question on this, and I know it's the way certification is done, and I'm not sure I followed all the conversations before that, but I'm trying to think about it just from a streamlined perspective. And if I'm way off base just tell me to drop it, but why are we accrediting validation entities to validate NVEs versus just accrediting NVEs from an accreditation entity? Why that double layer?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

I think it's just like the EHR certification—that ONC basically validates a set of certifying bodies, and then those certifying bodies do the actual certification.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Right.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, and I guess I'm challenged. I'm questioning why. I know that's the model, and maybe it's working great for certification of EHRs. When I look at the CTEs, and I think about it and some of what I was reading in the RFI around the different types of NVEs and having different types of services, it seems like it could be very variable and not standard from—one certification body allows for self-attestation, and another one doesn't. So from a governing perspective, to me it feels like there's an extra layer in there. There are a lot of situations or businesses that either self-regulate or just go through a straight accreditation process. They're not accrediting certifying bodies.

Claudia Williams – Office of the National Coordinator

Micky, you probably know more than I do here, but one of the interesting roles that the first layer plays is to help with the testing tools so that—you can imagine a scenario where you make the testing tools super easy, and everyone, the certifying bodies, are like, "Just come to mine because it'll be the easiest one you want to do." The evaluation buddy. So there is a check and balance in providing another entity that can govern the testing tools that are—not the whole process around validation but the testing … requirements. That's one of the nice checks and balances we have in the EHR certification process.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right. And that was actually one of the first early principles, I think, that came out of the certification adoption workgroup very early on was that there should be separation of the organization that is creating the standards from those that do the testing. They saw that as a problem in CCHIT, for example, which is why they recommended breaking that apart.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Okay.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

And remember, if it's done by ONC or some pure governmental agency, there's lots of budgetary and other issues that accrue to that. Whereas if you're able to do it, again, more on a more voluntary basis but they have to do it under some accreditation that, again, is still voluntary, that solves that problem. And they can charge for it so that you then don't have to have a line item in the budget or anything.

Claudia Williams – Office of the National Coordinator

Yeah, I'm not saying ONC needs to be the accreditation. I understand the point on checks and balances; it just seems that there could be a lot, almost too much, variability to—it just seems like there'd be more variability and less consistency, and I wonder if that's a question in terms of just gaining trust around this whole area.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Right. That'd be up to the accrediting agency to make sure the variability was less and that you didn't have someone who was giving away a validation.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Claudia Williams – Office of the National Coordinator

Yeah. Again, I was thinking of hospital systems. I was thinking of IRBs. I was thinking of other models where there's a single accrediting body entities have to pay to be accredited, but it's a standard, and there are often even site visits and—I'm not looking to make this more bureaucratic, I'm actually trying to streamline this a little bit to say that—with some peer monitoring. So in thinking about alternative approaches, I was just questioning whether this is the most streamlined and efficient way to do this with the least variability to get us to where we want to be. That was the rationale behind the question.

Peter DeVault – EPIC Systems Corporation

This is Peter. I'd actually like to step back a little bit and suggest that one of the things that I've thought about this RFI is that it focuses too much on the aspect of governance—that is, certification or whatever we want to call it—of the technologies and the intermediaries.

In our customer experiences that have been participating in exchanges, the other crucial aspect that's allowed them to have that layer of trust that allows interoperability to happen is having escalation and grievance procedures in place so when there's a question between two organizations who are sharing information about whether the rules of the road were followed, that there are institutions in place and procedures in place for addressing those.

That's an aspect of governance that this RFI doesn't seem to contemplate at all, and it seems to me like it would be very useful to have a model to give to states or other exchanges for how that aspect of governance might work.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

So the accrediting agency in this case would have appeals authority, because you'd say the NVE—

Peter DeVault – EPIC Systems Corporation

There's two kinds of grievances that there might be, right? There's a grievance that, in fact, this NVE that was certified actually in the real world doesn't live up to what it was supposed to be certified for, but then there's also the aspect of what one end healthcare system might have a grievance with another healthcare system on the network if they believe that they weren't faithfully representing a treatment relationship with the patients or something like that.

Amy Zimmerman – Rhode Island Department of Health & Human Services

That sounds like more under the—I'm trying to think back to the categories of whether it falls under a CTE, but it sounds like it's a higher level because it's more the function, the governance function, at the highest level, not what each NVE has to do.

Peter DeVault – EPIC Systems Corporation

Correct. Right. It's how the entire ecosystem works together.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Right.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Who does oversight.

Claudia Williams – Office of the National Coordinator

Hey, Peter, I'm just trying to understand. So would it be that I complain about XYZ NVE and the endgame is they can be blacklisted? Is it a complaint vis-à-vis their status as an accredited body, or more even as a support to mediate the differences between two organizations?

Peter DeVault – EPIC Systems Corporation

Right. Mediating the differences between the two organizations and the range of—as our organizations have gone through this and talked about it—the range of outcomes is pretty broad. Most of the time disagreements between parties can be simply mediated and people would agree to behave differently in the future, all the way up to some kind of blacklisting thing, which has never actually happened. So there might be a whole range of potential complaints and potential outcomes from those.

Amy Zimmerman – Rhode Island Department of Health & Human Services

But I would say that—sort of getting to that point—while it may be mediation between two parties, I could clearly see that if there was some sort of NVE that was violating the CTEs or not living up to what it said and somebody else, another entity, reports them, then it could trigger a grievance or an appeal and some sort of—for lack of a better term—investigation. And I guess the worst case scenario is they'd be stripped of their certification, which could affect funding or other things. I'm thinking about, again, different types of situations, whether it's hospitals, whether it's institutional review boards, if they don't follow the rules, there is a price to pay.

It doesn't mean that you don't give them a fair process—now I'm thinking really in regulatory rules—or they have to give a remediation plan and have so many days to correct whatever they have technically violated according to these CTEs. But I think it's a point very well taken.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

So this would be about saying that that needs to be an element of governance. And is that also a suggestion that there should be a CTE related to that?

Peter DeVault – EPIC Systems Corporation

Well, I'm not sure CTEs are even the right way to approach it. It's almost as though we need some kind of model that we can show to people of how these processes might work within an exchange—so a model grievance and appeals process.

Amy Zimmerman – Rhode Island Department of Health & Human Services

This is where I think—I think that this kind of stuff would fit at the accreditation. This is where I was kind of trying to go, and maybe I wasn't saying it well. But when you have a single accrediting body—or maybe it's the certification body; I don't know—if you have a single accreditation body, then that accreditation body if someone says this rule or requirement is being violated, the accreditation body could then trigger an investigation and say, "Gee, we're not going to continue to accredit you because you're not following the rules."

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Right. The accreditation body says to the validation bodies, "You must have an appeals process and an ability to address complaints through some compliance mechanism." And therefore, it's then up to the compliance bodies or the validation bodies to institute that in some fashion.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Right.

Amy Zimmerman – Rhode Island Department of Health & Human Services

I mean, that actually adds another layer because if somebody tries to get certified through a validation entity, and the validation entity says no, and they feel that they are meeting the criteria and the validation entity feels they shouldn't, then do they go to the accrediting body? I mean, that's sort of a third layer.

Dave Goetz – OptumInsight – Vice President for State Government Solutions

Well, they go to another validation body. I think that's a marketplace. I think that could be dealt with by the marketplace.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yeah, and can't we just draw the analogy from EHR certification? I mean, if you as an EHR vendor are upset in some way with the process—I don't know how that works. You just go to another one to Dave's point. If on the other hand you are a user, and you feel that an EHR vendor has violated their certification requirements, then you can appeal to the certification body, I think, right? And I think there's a process for that.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah. Although I have a little bit of a problem from just thinking about it from the point you say—whether I'm an NVE or an EHR company or whatever—I can't get certified under one group, so I'm going to go off to another and see if they'll accept the same thing that I'm doing. That doesn't lead to trust. That leads to variability that creates problems. That's kind of where my comments are coming from.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

It depends on how strong your policy's enforcement are, right? Because I don't know that there's been that issue in the EHR world.

Claudia Williams – Office of the National Coordinator

Guys, it's two minutes before—let me suggest, Micky, would mind just wrapping, kind of summarizing this one, and then we should open for public comment right after that—but great progress.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

I think on this one we were on question two, right? I don't know that we really got—it's a very, very broad question, so I don't know that there was any specific comment that I could even pull out of the discussion of this question, in part because it's so broad. But I welcome anyone else who wants to put a little more flesh on the bones of that one.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Well, I think as a result of that question—the question that got raised—starting to discuss that raised another question, which is where in the RFI do we—that we believe, or do we believe—I mean, do we have consensus that we believe that there needs to be some sort of complaints and grievance process at an overarching level for NVEs and their relationship with each other and how—if anyone feels that an NVE is not living up to the requirements, how do they address that?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

That's right. Yeah, thanks for reminding me.

Claudia Williams – Office of the National Coordinator

Then to Amy's point, you could say something like the risks of having multiple layers and multiple validation entities is variability, and any consistency—that hasn't been a problem in the EHR space necessarily, so that would mean that you'd have a clear and consistent enough set of policies that they could be applied across multiple—is there some way to say there's a risk created there; we seem to have addressed it for EHRs; and the parallel would be then sufficiently tight and clear that you end up with relative consistency across multiple entities?

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yep. Yeah, I think that's right. So that's the concern. You just have to strike the right balance. So I think if everyone's okay with this, maybe we can ask for e-mail comments on some of the other ones? The ones that strike me, I'll just say, as being worthy of everyone just giving a quick look at and your reaction to is question 3; how urgent do we feel? How great is the urgency for a nationwide governance approach?

I think that there is also a good one in question 58, which is this question of should there be different bundles. The reason I raise that one is even if we don't do it in this workgroup, that's going to be an issue that comes up in our workgroup conversations because it came up in one of the other subgroups where the question is—Peter Carl was on that call. There's sort of a question of whether we actually have more focused bundles of CTEs that vary according to the type of exchange or the type of use case you're talking about. So you wouldn't try to say that there is a single set of CTEs that applies to everything because that wouldn't make sense.

Peter DeVault – EPIC Systems Corporation

Different ecosystem architectures would make …

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Exactly. Yeah, and even going so far as I think that that workgroup is going to be recommending—in the way of standards, for example, a voluntary—rather than having a governance process that requires a set of standards—having a more voluntary approach that says that NVEs ought to be able to—that the role of governance here is transparency and information availability to the market, and so that NVEs ought to just declare which standards they are using and make that available to the market, and then those standards would be appropriate for the type of transactions they plan on conducting, and to the extent that there is overlap in a use case that's covered by EHR certification, then you'd want those to be the same. But otherwise just allow people to essentially—I think, as Carl said—earn CTEs according to what it is they want to do.

Claudia Williams – Office of the National Coordinator

We do have another call Monday at—gosh, we unfortunately have these late-day calls—but it looks like it's Monday at 4:00 to 5:00. And then this group will be presenting back—actually, it won't be presenting. Our proposed approach was actually that this group obviously was going to present anything that needs to be, but would just be e-mailing comments at night. So, Micky, your idea of having people pre-populate comments would be a really good one because we're going to have a very quick turnaround for the next day.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Yep.

Claudia Williams – Office of the National Coordinator

Are MacKenzie or Mary Jo on the line?

MacKenzie Robertson – Office of the National Coordinator

Yes, I'm here. Sorry, could you repeat that?

Claudia Williams – Office of the National Coordinator

Do you want to open up the lines?

MacKenzie Robertson – Office of the National Coordinator

Sure. Operator, could you please open the line for public comment?

Public Comment

Operator

Sure. If you are on the phone, you can press *1 at this time to speak. If you're listening via your computer speakers, please dial 1-877-705-2976 and press "1" to be placed into the comment queue. We do not have any comments at this time.

MacKenzie Robertson – Office of the National Coordinator

Thank you.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Okay. Well, great. Thank you everyone. I think we made great progress to the task we had at hand, and any thought you have via e-mail on these other secondary ones, particularly around urgency and then bundling, I think would be very helpful and informative for the workgroup conversations next week.

Claudia Williams – Office of the National Coordinator

Thank you guys so much.

Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer

Great. Thanks, everyone.

Dave Goetz – OptumInsight – Vice President for State Government Solutions
Thanks. Have a good weekend.

Amy Zimmerman – Rhode Island Department of Health & Human Services
Thank you.